

## ENZYMATIC THERADY

INCORPORATED

What Better feels like."

### INTEGRATIVE THERAPEUTICS INC."

NF Formulas + PhytoPharmica Tyler Encapsulations + Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 \* F: 503.582.0467

#### ENZYMATIC THERAPY ٤ĸ PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 • F: 888.570.6460 (Enzymatic) P: 920.469.9099 • F: 920.469.4418 (Phyto)

SFF

September 20, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® CoQ10	The purest, natural form of coenzyme Q10 to support heart, brain, skin, and periodontal health and promote healthy aging.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	•
•	Robert C. Doster
Title:	Senior Vice President of Scientific Affairs
Date:	9/20/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Financial Officer

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Vitaline CoQ10 55e



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September 21, 2004

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RE:

Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT		INGREDIENT(S) TO WHICH
Vitaline® CoQ10	Provides superior support for overall health, specifically heart, brain, skin and periodontal function.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: FLICIL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 921/04

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Sincerely,

Michael P. Devereux Chief Financial Officer